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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,991	02/15/2000	Frank Uhlmann	0652.2040000/REF	3282

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Sterne Kessler Goldstein & Fox PLLC
Attorneys at Law
1100 New York Avenue N W
Suite 600
Washington, DC 20005-3934

EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/500,991	UHLMANN ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,37,40,41,43,44,46-49,58 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,37,40,41,43,44,46-49 and 58* is/are rejected.

7)☒ Claim(s) *59* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 36, 37, 40, 41, 43, 44, 46-49, 58, and 59 are pending and under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 36, 37, 40, 41, 43, 44, 46-49, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (reference AJ cited in PTO 1449 dated 08/03/2000) in view of Nagase et al. (DNA Res. 1996 Feb 29;3(1):17-24; reference of record) and Nomura et al. (DNA Res. 1994; 1(5):223-9; reference of record).

The reference teachings and rejection made of record are restated below.

Brown et al. teach a high-throughput fluorometric process for measuring protease activity comprising contacting a flurogeneic peptide labeled at one end with a UV/blue fluorophore and at the other end a quencher in the presence of an inhibitor test compound (see entire publication, especially **Discussion** section on pp. 155-157). Brown et al. does not teach incubating with a test compound a separin in the presence of a separin substrate.

Nagase et al. teach the cDNA KIAA0165 (see entire publication, especially Table 1 on p. 19). Waizenegger et al. (Cell. 2000 Oct 27;103(3):399-410) provide evidence that KIA0165 is the human separin, which is the protease for human SCC1 and is involved in sister chromatid separation (see entire publication, especially p. 408, left column, lines 6-28; and p. 409, right column, line 26). Thus, Nagase et al. teach the human separin encoded by cDNA KIAA0165.

Nomura et al. teach the cDNA KIAA0078 (see entire publication, especially Table 1 on p. 226). Sumara et al. (J Cell Biol. 2000 Nov 13;151(4):749-62) provide evidence that KIAA0078 is the human SCC1 (see entire publication, especially p. 750, right column, section titled ***cDNA Clones,*** lines 37-38). Thus, Nomura et al. teach the human SCC1 encoded by cDNA KIAA0078.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Brown et al. such that the human separin taught by Nagase et al. and the human SCC1 taught by Nomura et al. is used in the process taught by Brown et al., where the human SCC1 is labeled at one end with a UV/blue fluorophore and at the other end a quencher. One of ordinary skill in the art at the time the invention was made would have been motivated to do this for the purposes of having a fast and simple process for identifying human separin inhibitors, which can be used as anti-cancer agents that inhibit sister chromatid separation in cancer cells.

No patentable weight is given to the preamble of these process claims since it merely recites the purpose of these process claims. Thus, the process steps of the modified Brown et al. process stated above renders the claims obvious because these process steps are the same as the process steps of the claims. Because the process steps of the modified Brown et al. process stated above are the same as the process steps of these claims, then the modified Brown et al. process would inherently identify compounds that inhibit sister chromatid separation in eukaryotic cells.

Claim 44 is also included in the rejection because no particular structural features are provided by the process that produces the substrate, which would distinguish it from the human SCC1 substrate taught by Nomura et al. Thus, no patentable weight is given to the process for producing the substrate.

Claim 47 is also included in the rejection because the human SCC1 substrate taught by Nomura et al. is deemed to be a "fragment or variant" of SEQ ID NO: 1. Furthermore, Hauf et al. (Science. 2001 Aug 17;293(5533):1320-3) provide evidence that human SCC1 has two separin cleavage sites (see entire publication, especially p. 1320, middle column, lines 11-13).

Applicants' arguments filed 06/06/2007 have been fully considered but are not persuasive for reasons of record as further explained below. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

According to MPEP §2112, claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter

sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Since Waizenegger et al. state above provide evidence that KIA0165 is the human separin, which is the protease for human SCC1 and is involved in sister chromatid separation, then Nagase et al. teach the human separin encoded by cDNA KIAA0165 which inherently has protease activity. Since Nomura et al. teach the cDNA KIAA0078 provide evidence that KIAA0078 is the human SCC1 (see entire publication, especially p. 750, right column, section titled ***cDNA Clones,*** lines 37-38), then Nomura et al. teach the human SCC1 encoded by cDNA KIAA0078 which inherently is a protease substrate for human separin.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Brown et al. such that the human separin taught by Nagase et al. and the human SCC1 taught by Nomura et al. is used in the process taught by Brown et al., where the human SCC1 is labeled at one end with a UV/blue fluorophore and at the other end a quencher, in order to have a fast and simple process for identifying human separin inhibitors, which can be used as anti-cancer agents that inhibit sister chromatid separation in cancer cells.

Conclusion

4. No claims are allowed.

5. Claim 59 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

TEKCHAND SAIDHA
PRIMARY EXAMINER